DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

94778d SAN2004-348

VIA FEDERAL EXPRESS
Our Reference: 3003383380

June 4, 2004

Robert B. Buck, President & Principal Owner
Million Air Monterey
100 Skypark Drive
Monterey, California 93940-5357

WARNING LETTER

Dear Mr. Buck:

On April 23, 2004, FDA conducted an inspection of your facility, located at 100 Skypark Drive, Monterey, California, which provides watering point and lavatory waste service as well as drinking ice to private, corporate, and charter aircraft at Monterey Peninsula Airport. The observations made during the inspection revealed that your facility is in violation of Section 361 of the Public Health Service Act and the Interstate Conveyance Sanitation regulations at Title 21, Code of Federal Regulations, Part 1250 (21 CFR § 1250). FDA's observations were listed on Form FDA 483, List of Inspectional Observations, a copy of which was provided to and discussed with Mr. George Taylor, Line Manager, at the conclusion of the inspection. A copy of the Form FDA 483 is enclosed for your reference.

During the inspection, the following observations were noted:

1. In accordance with 21 CFR § 1250.82(e), there shall be no backflow between portable water systems and any other systems. However, there is no backflow prevention device on the hose used to fill the lavatory cart with water to make the bluing solution used for lavatory flushing aboard the aircraft.

2. In accordance with 21 CFR § 1250.67(a), all servicing area piping systems, hydrants, taps, faucets, hoses, buckets, and other appurtenances necessary for delivery of drinking and culinary water to a conveyance shall be designed, constructed, maintained and operated in such a manner as to prevent contamination of the water. However, the fill hose for the potable water cart was stored in a dirty bucket filled with dirty standing water.

3. In accordance with 21 CFR § 1250.28, all ice coming in contact with food or drink shall be stored and handled in such manner as to avoid contamination. However, the ice machine had ice scoops stored on top of it in contact with a dirty surface which was also used by employees to store rain gear.

The list of inspectional observations, identified above, is not intended to be an all-inclusive list of the conditions observed at your facility. It is your responsibility to assure adherence with all applicable statutes and regulations enforced by FDA.

Based on the inspectional findings, we are classifying your facility as "Provisional" for interstate carrier use for a period of thirty days. A "Provisional" classification means that the facility may continue to operate; however, significant correction of violations must be made by the expiration date. On or about that date, a re-inspection of this facility will be conducted to assure that corrections meet FDA requirements. If significant corrections are not made by the time of the next inspection, this facility will be reclassified as "Not Approved" for carrier use. Assignment of "Not Approved" status means that water, waste service, and drinking ice will be prohibited from use by interstate conveyances at your Monterey, California facility until the violations have been corrected and the facility has been re-inspected by FDA.

You should notify this office in writing, within fifteen working days of the receipt of this letter, of the specific steps that you have taken to prevent a recurrence of the cited deficiencies. Your response should include an explanation of each step being taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 30 days, state the reason for the delay and the date by which the corrections will be completed. Include copies of any available documentation demonstrating that corrections have been made. Your response should be directed to:

Randall P. Zielinski, CSO/ITS
U.S. Food and Drug Administration
1431 Harbor Bay Parkway
Alameda, CA 94502-7070

You may wish to fax your response to Mr. Zielinski at (510) 337-6703.

Sincerely,

Barbara Cassens

Barbara J. Cassens
District Director
San Francisco District

Enclosure: Form FDA 483